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ORIGINAL ARTICLE

Use of audiovisual devices in transnasal endoscopy without sedation to improve tolerance. A prospective clinical trial

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KEYWORDS
Transnasal endoscopy;
Tolerability;
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Abstract
Introduction and aim: Transnasal endoscopy (TNE) has proven its diagnostic utility, but it has not been widely accepted given that it is performed without sedation. There are no previous studies on the use of methods to improve its tolerability. Our aim was to evaluate the tolerability of TNE, when simultaneously performed with an audiovisual device as a distractor.
Methods: We evaluated 50 patients, 10 of whom did not agree to participate. The performance of the procedure was explained, using an audiovisual device. Before randomization, we applied anxiety and depression scores. Patients were divided into 2 groups: Group I (using an audiovisual device during the procedure) and Group II (without a device). Anxiety and numeric pain rating scales were used, and vital signs were monitored and recorded before, during, and after the endoscopy. An overall procedure satisfaction score was applied at the end of the study and 24 h later.

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Results: Mean age was 41.6 years and 35 of the patients were women (87.5%). The most frequent indication for TNE was refractory gastroesophageal reflux disease. There were no severe comorbidities, and none of the patients had a significant anxiety or depression score. One patient in Group II did not tolerate TNE due to nasal pain. There was no statistically significant difference between groups, regarding anxiety, pain, vital signs, and satisfaction scale.
Conclusion: Our study showed that TNE was well tolerated and had a high acceptance rate in our patients. The use of distracting audiovisual devices did not increase tolerance to the endoscopic procedure.

PALABRAS CLAVE
Endoscopía transnasal;
Tolerabilidad;
Distractores audiovisuales

Uso de dispositivos audiovisuales en endoscopia transnasal sin sedación con el objetivo de mejorar la tolerancia. Estudio clínico prospectivo

Resumen
Introducción y objetivo: La endoscopía transnasal (ETN) ha probado su utilidad diagnóstica; sin embargo, no se ha aceptado de manera generalizada debido a que se realiza sin sedación y no se han realizado estudios que reporten el uso de métodos que mejoren su tolerabilidad. El objetivo fue evaluar la tolerabilidad de la ETN cuando se realiza de manera simultánea con un dispositivo audiovisual como distractor.
Métodos: Se evaluaron 50 pacientes, 10 de ellos rechazaron participar. El procedimiento se explicó utilizando un dispositivo audiovisual. Antes de la aleatorización, se aplicaron escalas de ansiedad y depresión. Los pacientes se dividieron en 2 grupos: Grupo I (utilizando un dispositivo audiovisual durante el procedimiento) y Grupo II (sin dispositivo). Se utilizaron escalas numéricas de ansiedad y dolor. Se monitorearon signos vitales antes, durante y después de la endoscopía. Se aplicó una escala de satisfacción al final del estudio y 24 horas después.
Resultados: El promedio de edad fue 41.6 años y 35 (87.5%) pacientes fueron de sexo femenino. La indicación más frecuente para ETN fue enfermedad por reflujo gastroesofágico refractario. No se encontraron comorbilidades significativas y ningún participante contaba con puntuación de ansiedad o depresión significativa. Un paciente del grupo II no toleró la ETN debido a dolor nasal. No se encontró diferencia significativa en niveles de ansiedad y dolor, signos vitales y escala de satisfacción entre grupos.
Conclusiones: Nuestro estudio mostró que la ETN es bien tolerada y tiene un porcentaje alto de aceptación en nuestros pacientes. El uso de dispositivos audiovisuales distractores no incrementó la tolerancia al procedimiento endoscópico.

Introduction and aim

Transnasal endoscopy (TNE) is a procedure performed through the nasal passage with an ultrathin endoscope (<6 mm diameter). It does not require general anesthesia, but instead, uses local anesthesia. The intervention was designed to diminish risk to the patient and healthcare-related costs. There are fewer undesirable side effects during TNE than those reported for conventional endoscopy, and most are easily manageable[1].

TNE reduces pharyngeal stimuli, resulting in reduced sympathetic response and cardiovascular stress, making it a tolerable procedure[2,3]. The diagnostic efficacy of TNE is comparable to that of conventional endoscopy[4,5].

Audiovisual distracting methods include audio and video stimuli to create an illusion of ''presence''. They have proved useful in reducing the pain and anxiety associated with several invasive medical procedures[6–9]. The main goal of the following study was to prospectively evaluate TNE tolerability and to determine the impact of distracting audiovisual devices on patient acceptance rate and tolerance to the procedure.

Methods

Fifty consecutive patients with an indication for upper endoscopy were evaluated within the time frame of May 2019 and February 2020. The inclusion criteria were age

>18 years and esophageal symptom presentation (globus, heartburn, regurgitation, and noncardiac chest pain). The exclusion criteria were progressive dysphagia, gastrointestinal bleeding, recent weight loss, history of food impaction episodes, chronic use of nonsteroidal anti-inflammatory drugs or anticoagulants, previous nasal trauma or surgery, chronic sinusitis, severe psychiatric disorders, or comorbidities (decompensated diabetes, chronic obstructive pulmonary disease, cardiopathy, asthma, previous esophageal surgery).

Patients were interviewed in a quiet environment, and the procedure was thoroughly explained. Before randomization, the Beck Anxiety Inventory and the Patient Health Questionnaire (PHQ-9)[10] were applied, and baseline values were recorded for each patient. The scales were applied by medical students and the endoscopists were blinded to the results.

The investigators arbitrarily selected the total number of patients in this prospective pilot study. Research Randomizer software (Copyright 1997–2020 Geoffrey C. Urbaniak and Scott Plous) (website www.randomizer.org) was used for randomization.

There were 2 groups of 20 patients each. Both groups received a brief description of the endoscopic procedure with the Oculus Go® virtual reality headset (Facebook Technologies, LLC), through videos and descriptive slides. This audiovisual content was designed by the Biomedical Engineering Department of our hospital. Group I participants underwent TNE while simultaneously using the audiovisual device, whereas conventional TNE was performed on Group II participants.

Patients reported pain and anxiety levels before, during, and after the procedure. A verbal numeric scale was used to evaluate pain (0 signifying no pain and 10 being the worst pain ever experienced); anxiety levels were evaluated from 0 to 10 (0 signifying no anxiety and 10 being the worst anxiety possible). The scales applied were downloaded from the Internet.

For the present study, intranasal and pharyngeal lidocaine-based gel and spray anesthesia were applied by the endoscopist to all the patients of each group, in a dose-response manner.

The endoscopic procedures were performed by 2 of our investigators (DEBS and JAGG) trained in transnasal endoscopic procedures. The nasal endoscope used for this study was the Fuji EG-530N model (Fujifilm Corporation™). During the procedure, vital signs and pain and anxiety levels were monitored and recorded, utilizing verbal numeric scales. The following variables were also recorded during the study: procedure duration, undesirable effects, complications, and endoscopic image quality. The satisfaction scale (with a 19-point maximum) was applied upon patient discharge and repeated 24 h after TNE. The scale was designed by 2 of the investigators (JAGG, DEBS) and evaluates the parameters of comfort, patient willingness to repeat and recommend TNE to other people, adverse effects, and the perception of care provided by the healthcare staff (Annex 3).

The questions asked in the satisfaction scale were the following:

- How do you feel regarding the procedure?
- If necessary, would you repeat the study in the same modality?
- Did you feel any pain during the study, or are you feeling pain right now?
- Would you recommend this endoscopic procedure modality to your family or friends?
- On a scale of 1 to 10, how do you feel you were treated?

Statistical analysis

The parametric variables were presented as mean and standard deviation and the nonparametric variables were expressed as median, proportions, and 25–75% interquartile ranges. A nonparametric variable comparison was made using the chi-square test, and the parametric variables were compared using the Student's t test. SPSS version 20 software (IBM SPSS Statistics for Windows, IBM Corp., Armonk, NY) was used. Significance was assessed at a p value <0.05.

Ethical considerations

Informed consent was requested from the patients to participate in our investigation. All participants were 18 years of age or older. Our research complies with the current regulations on bioethics research, was authorized by the ethics committee of our institution (*Hospital Universitario ''Dr. José Eleuterio González''*). The authors declare that this article contains no personal information that could identify the participants of our research.)

Results

Patients

Of the 50 patients, 40 were included. Ten patients did not agree to participate because they stated they were afraid to remain conscious during the procedure. The patients were divided into 2 groups of 20 patients each, by simple randomization. The intervention group (Group I) was exposed to a distracting audiovisual device during TNE and the control group (Group II) was not.

The majority of the patients included in the study (72.5%) had no comorbidities. The most frequent comorbidity was arterial hypertension in 4 patients (10%). The most common pre-endoscopic diagnoses were refractory gastroesophageal reflux disease (GERD), GERD with dyspepsia, or GERD with globus. Endoscopic findings were normal mucosa (100%), hiatal hernia (17.5%), atrophic gastritis (80%), erosive gastritis (17.5%), fundic gland polyps (5%), food residue (2.5%), and duodenitis (5%). Biopsies were taken in 97.5% of the patients (Table 1).

Groups

There was no statistically significant difference between groups regarding age (Group I: 42.85 ± 9.08, Group II: 40.05 ± 11.8 years, p = 0.76). The Beck Anxiety Inventory applied before randomization produced a score of 14 in Group I and 13.5 in Group II; both were considered normal or mild anxiety values (p = 0.71). The PHQ-9 score in Group I was 6.2 ±

Table 1 General patient characteristics and endoscopic findings.

Characteristics	n (%)
Sex	40 (100)
Female	35 (87.5)
Male	5 (12.5)
Previous diagnosis	40 (100)
Dyspepsia	6 (15)
Dyspepsia + GERD	14 (35)
Refractory GERD	16 (40)
Refractory GERD + NCCP	1 (2.5)
Dyspepsia + globus	2 (5)
Globus + GERD	1 (2.5)
Comorbidities	
None	29 (72.5)
Rheumatoid arthritis	2 (5)
Dyslipidemia	2 (5)
Diabetes mellitus	1 (2.5)
Arterial hypertension	4 (10)
Hypothyroidism	1 (2.5)
Thyroid nodule	1 (2.5)
Osteoarthritis	1 (2.5)
Allergic rhinitis	1 (2.5)
Asthma	1 (2.5)
Adverse effects	
Intolerable pain	1 (2.5)
None	39 (97.5)
Endoscopic findings	
Esophagus	
Normal	40 (100)
Stomach	
Food residue	1 (2.5)
Atrophic gastritis	32 (80)
Fundic gland polyps	2 (5)
Erosive gastritis	7 (17.5)
Duodenum	
Normal	37 (92.5)
Erosive duodenitis	2 (5)
Not visualized	1 (2.5)
Biopsy	
Yes	39 (97.5)
No	1 (2.5)
Hiatal hernia	
Yes	7 (17.5)
No	33 (82.5)
Endoscopist visibility (good, fair, poor)	
Esophagus	G: 40 (100) F: 0 (0) P: 0 (0)
Stomach	G: 39 (97.5) F: 0 (0) P: 1 (2.5)
Duodenum	G: 40 (97.5) F: 0 (0) P: 1 (2.5)

[a]Conventional endoscopy was performed. Group II patient.

5.2 and 5.4 ± 5.4 in Group II, with values ranging from normal to mild depression (p = 0.74). Said findings are described in Table 2.

There was no statistically significant difference between the groups, with respect to vital signs. The mean procedure duration in Group I was 15.7 ± 4.1 min, and 16.7 ± 3.2 min in Group II (p = 0.98); no statistical significance was found (Table 3).

Regarding anxiety and pain levels during and after the procedure, a tendency toward the intervention group was found (129.5 ± 12 vs. 141.7 ± 23 mmHg, p = 0.055, and 1.32 ± 1.73 vs. 2.04 ± 2, p = 0.06) (Table 4).

A patient from the control group presented with intolerable pain in the nasopharynx and the procedure was suspended, but the patient was included in the statistical analysis.

The results of the comparison of the satisfaction questionnaire applied in Group I and Group II, immediately after TNE and 24 h later, were: 16.68 ± 2.47 vs. 16.27 ± 2.6 and 16.22 ± 1.73 vs. 16.5 ± 1.7, respectively, out of a maximum possible score of 19 points. The acceptance rate immediately after TNE and 24 h after the procedure were similar in both groups (Group I 86.3% vs. Group II 85%) as shown in Table 5.

Discussion

The results of our study suggest that TNE has a high acceptance rate and is well-tolerated. The use of distracting audiovisual devices during the procedure did not appear to offer additional advantages, compared with conventional TNE.

TNE is currently considered a reasonable alternative to conventional endoscopy. It offers the following benefits: it does not require general anesthesia, patients experience a faster recovery, there are fewer adverse effects, and it costs less than conventional endoscopy. It also provides similar diagnostic performance. A total of 72.5% of the study participants did not have any comorbidities, but transnasal (or even transoral) endoscopy performed with an ultrathin instrument and no sedation may have a role, with respect to tolerance, in patients at the opposite end of the spectrum (i.e., those with severe comorbidities). In the absence of readily available anesthesia support, such an approach to upper endoscopy may be an effective and safe recourse in many healthcare settings.

The rate of diagnosis of atrophic gastritis was considerably high (80% of all cases), which could be due to having a preselected population that presented with dyspepsia and esophageal symptoms.

To the best of our knowledge, the use of virtual reality devices for explaining the procedure and improving patient tolerability during TNE—a tool that is easy to use and comfortable for the patient—has not been evaluated. A Cochrane review published in 2012[11] reported the experience with and benefits of audiovisual distraction, with some studies providing evidence of the intervention having an effect on anxiety. However, data are scarce for conclusive results. The benefits of audiovisual distraction with more meaningful audiovisual input should be addressed in future prospective studies.

Table 2 Description of variables by group (sex, mean age, anxiety and depression scores).

Variable	Group I	Group II	p value
Sex (M, F)	(2 M,18 F)	(3 M, 17 F)	
Mean age (years)	42.85 ± 9.08	40.05 ± 11.8	0.764
Beck Anxiety Inventory score	14 ± 10.8	13.5 ± 9.4	0.711
PHQ-9 score	6.2 ± 5.2	5.4 ± 5.4	0.640

Table 3 Vital signs and endoscopy duration by group.

Parameter	Group I	Group II	p value
Initial systolic BP (mm Hg)	129.2 ± 17.4	135.6 ± 27.1	0.380
Initial diastolic BP (mm Hg)	81.9 ± 8.9	80.75 ± 12.56	0.741
Initial heart rate (bpm)	79.9 ± 10.8	78.0 ± 15.3	0.654
Initial SO_2 (%)	97.9 ± 1.6	98.1 ± 1.3	0.676
Procedure systolic BP (mmHg)	136.3 ± 17.4	143.8 ± 21.95	0.251
Procedure diastolic BP (mmHg)	83.58 ± 11.59	88.15 ± 13.75	0.270
Procedure heart rate (bpm)	87.47 ± 12.07	91.65 ± 19.32	0.426
Procedure SO_2 (%)	98.5 ± 1.3	98.1 ± 1.1	0.288
Final systolic BP (mmHg)	129.5 ± 12.15	141.79 ± 23.42	0.055
Final diastolic BP (mmHg)	82.28 ± 10.47	87.63 ± 13.86	0.196
Final heart rate (bpm)	84.89 ± 14.47	87.6 ± 14.72	0.572
Final SO_2 (%)	98.22 ± 1.26	98.4 ± 1.3	0.591
Endoscopy duration (min)	15.7 ± 4.10	16.7 ± 3.2	0.918

Table 4 Pain and anxiety numerical scales by group.

Parameter	Group I	Group II	p value
Anxiety BEFORE (0—10)	1.05 ± 1.9	1 ± 1.4	0.927
Anxiety DURING (0—10)	1.32 ± 1.73	2.4 ± 2.06	0.069
Anxiety AFTER (0—10)	0.84 ± 1.21	1.2 ± 1.54	0.427
Pain BEFORE (0—10)	0 ± 0	0 ± 0	1
Pain DURING (0—10)	1.0 ± 1.8	2.3 ± 2.94	0.09
Pain AFTER (0—10)	1.47 ± 0.74	1.44 ± 0.81	0.918

Table 5 Satisfaction questionnaire at 0 and 24 h after the procedure.

Parameter	Group I	Group II	p value
Question 1 0 h	0.84 ± 0.37	0.89 ± 0.809	0.798
Question 1 24 h	0.87 ± 0.352	1.06 ± 0.854	0.416
Question 2 0 h	1.74 ± 0.653	1.79 ± 0.535	0.787
Question 2 24 h	1.67 ± 0.724	1.67 ± 0.724	0.725
Question 3 0 h	0.84 ± 0.375	0.58 ± 0.507	0.077
Question 3 24 h	0.69 ± 0.479	0.69 ± 0.479	0.247
Question 4 0 h	1.74 ± 0.653	1.74 ± 0.562	1.00
Question 4 24 h	1.67 ± 0.724	1.63 ± 0.806	0.881
Question 5 0 h	10 ± 0	9.94 ± 0.229	0.324
Question 5 24 h	9.73 ± 1.033	9.94 ± 0.250	0.449
Mean 0 h (max 19)	16.68 ± 2.47	16.22 ± 1.73	0.517
	87.3%	85.36%	
Mean 24 h (max 19)	16.27 ± 2.60	16.53 ± 1.76	0.745
	85.2%	86.4%	

When evaluating anxiety and depression, we found that most of our patients had no anxiety or depression, or their presentation was mild, according to the questionnaires applied.

Procedure duration was similar between the 2 groups, correlating with the length reported for an upper gastrointestinal endoscopy study[12]. Mosso-Vázquez et al.[13] currently described significantly lower respiration rates, overall pain, and anxiety levels, in patients undergoing upper gastrointestinal endoscopy, with local anesthesia and virtual reality supplementation. Even though no statistically significant differences were found between our pilot study groups, regarding vital signs and pain and anxiety levels before, during, and after TNE, there was a tendency towards lower blood pressure at the end of the nasoendoscopy and lower anxiety levels during the procedure in Group I (intervention group). This important finding should be addressed in future prospective trials, with a higher number of patients.

The quality of the endoscopic images of the mucosa was graded as good and satisfactory in 97% of the endoscopies (Table 1). The endoscopic diagnosis consisted of benign entities with mild symptoms, occasionally interpreted as functional disorders.

In our study, the general acceptance rate of TNE was 80%, much higher than the rate reported in a study conducted in the United Kingdom. TNE was indicated for Barrett's esophagus surveillance, and the reported acceptance rate was 27%[14]. The difference between the 2 studies could be explained by the fact that our patients were previously interviewed, and the procedure was thoroughly explained, with the support of the virtual reality device. We cannot rule out that other factors, such as cultural and socioeconomic variables, could influence the acceptance rate.

Most of our patients (85%) expressed that they would repeat TNE, if necessary, and that they would recommend this endoscopic modality to other people. We are aware that patients with higher anxiety or depression levels could reject or not tolerate the procedure. Panic attacks have been previously reported during TNE[15]. In such a context, carrying out meticulous patient selection to assess who is a candidate for this endoscopic procedure is vitally important.

We believe that a distracting audiovisual device could be useful and should be evaluated in patients that have previously rejected TNE or present with more severe anxiety and depression.

To the best of our knowledge, this is the first study conducted in Mexico that evaluates the tolerability of TNE. However, limitations of our study include the small sample, made up of a majority of female patients, and participants with no severe comorbidities or no anxiety or depression, or with a mild presentation of those affective conditions. Furthermore, patients with clinical warning signs of gastroesophageal diseases were excluded. We also considered the possibility of performing automatic patient selection because 20% refused to participate. Said refusal was probably due to the fact that those patients presented with severe anxiety or depression, even though the questionnaires applied to them did not reveal such high levels of those conditions.

Our results should be interpreted with caution, when extrapolating them to other groups with different clinical and demographic features and with several comorbidities. Nonetheless, in other TNE studies conducted on patients with several comorbidities, results have been satisfactory, reporting only minor complications, with epistaxis the most frequent, in 1–5% of the patients[16].

Transnasal endoscopy can be considered an optimal diagnostic intervention for non-complicated gastroesophageal diseases (Barrett's esophagus surveillance and complete intestinal metaplasia, as well as for gastric and esophageal biopsy sampling), in patients with mild anxiety.

Our findings are limited by the relatively reduced sample size and the fact that the satisfaction scale was created and designed exclusively for analysis in the present study. In addition, we excluded 10 patients that did not accept to participate in the study out of fear, which could be an unfortunate pre-selection bias, given that the group of self-excluded patients might have benefited the most from the study intervention. Said benefit should be addressed in prospective studies. Despite the limitations of the study, its data provide valuable information that can help public health agencies in Mexico, and in other countries with similar healthcare programs, to plan and make decisions, in the absence of readily available anesthesia support, and consequently save resources in many healthcare settings.

Conclusions

TNE is a diagnostic procedure for gastroesophageal diseases that is safe, tolerable, and has a good acceptance rate. It also provides a high level of satisfaction in patients that have no complications, few comorbidities, and mild anxiety or depression. In that group of patients, distracting audiovisual devices had no impact on improving tolerance to the procedure.

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Conflict of interests

All of the participants in this research declare that there was no conflict of interest during the development of our work and the creation of the manuscript.

Annex. Additional material

Additional material pertaining to this article can be consulted in the online version at doi:https://doi.org/10.1016/j.rgmx.2021.11.012

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